

REMARKS

A. Amendments in the specification

Insertion of a new paragraph on page 1 is requested to provide cross-reference to a copending application having related subject matter.

Paragraphs on pages 1–2 are amended to replace “WO 94/07568” with “WO 94/07468” in order to correct a typographical error. The cited document was correctly cited as WO 94/07468 in the Information Disclosure Statement (IDS) submitted on October 8, 2003. The Examiner’s consideration of that IDS is hereby acknowledged.

The paragraph bridging pages 1 and 2 is amended to delete discussion therein of a cited background reference (International Patent Publication No. WO 99/49852) to avoid any possibility of that discussion being potentially construed as mischaracterizing the disclosure of WO 99/49852. To the extent that any part of the wording of the now-deleted passage could be construed as mischaracterizing in any manner the disclosure of WO 99/49852, such wording was inadvertent and without deceptive intent, and Applicant invites the Examiner to read WO 99/49852 to determine what is disclosed therein.

Paragraphs on page 3 and bridging pages 9 and 10 are amended to be in alignment with Claim 1 as amended herein. As explanation of these amendments, see the remarks below relating to amendment of Claim 1.

B. Amendments in the claims

The following claims are now pending in the present application: Claims 1–14. Applicant respectfully notes an incorrect statement in the Office Action Summary that Claims 1–12 are pending in the application. Applicant confirms that Claims 1–14 remain pending in the application, as specified in the Detailed Action.

Claim 1 is amended to recite that the self-adhesive matrix “comprises” rather than “consists of” a solid or semi-solid polymer as further defined in the body of the claim. This amendment from language that could be construed as “closed” to explicitly open-ended language is made in the interests of clarity and finds support throughout the specification as filed. For example, although the matrix in “a particularly preferred embodiment” is described at page 10, lines 24–34 as being free of particles such as silica particles, it is implicit in this

description (and by differentiation of Claim 10 over Claim 1) that the TDS can, in its broadest embodiment, have such particles in the matrix. Further, the specification at page 13, lines 4–15 describes “a further preferred embodiment” wherein the TDS “further includes a crystallization inhibitor”. That a crystallization inhibitor (*e.g.*, polyvinylpyrrolidone) can be present as an additional component of the matrix (as opposed to the backing layer or removable protective sheet) is clear at least from the description of Invention Example 1, especially at page 15, lines 15–32. This description also shows that other materials can be present in the matrix, such as sodium bisulfite, ascorbyl palmitate and DL- α -tocopherol. The original use of “consisting of” language in Claim 1 and in various passages of the specification was an inadvertent error, made without deceptive intent, it being clear from the specification as a whole that other optional ingredients could be included in the matrix.

Claim 1 is further amended to clarify that the multitude of microreservoirs optionally contain one or more components in addition to the amine functional drug, one such optional additional component being a crystallization inhibitor. Support for a crystallization inhibitor as an optional component of the microreservoirs is found in the specification as filed, at least at page 7, lines 8–9. That the rotigotine of the microreservoirs is additional to that saturating the polymer is clear from, and supported by, the specification as filed, at least at page 6 line 35 – page 7 line 4.

Claim 1 is still further amended to remove the recitation that the matrix is saturated with the amine functional drug. As stated in the specification at page 6, line 37 – page 7, line 4, the presence of drug in microreservoirs within the matrix “does not exclude and will normally even imply that a certain fraction of the amine functional drug is dissolved in the ... matrix at its saturation concentration.” In other words, it is likely, but not certain or essential, that the matrix is saturated with the drug.

Claim 1 is still further amended to remove the adverb “highly” as a qualifier of “permeable” and to insert the adverb “substantially” as a qualifier of “impermeable”. One of skill in the art reading the specification as a whole will understand (a) that the degree of permeability to the free base form of the drug is merely sufficient to provide acceptable flux – see, for example, the specification as filed at page 10, lines 18–19; and (b) that

“impermeable” is not to be construed in an absolute sense, particularly in light of the disclosure in the specification as filed at page 7, lines 16–22, that some residual amount of the drug in salt form can be present in the matrix.

Claims 1–12 are amended to replace “characterized in that” or “characterized in” with “wherein”, to present these claims in a form more in accordance with standard U.S. claim drafting practice.

Claims 11–13 are amended to delete the word “type” appended to “silicone”, to further enhance clarity of these claims without affecting the meaning or scope of the claims.

Opportunity has been taken, in amending the claims, to correct typographical errors, to rephrase where it has been desirable to do so for enhanced clarity, and to present subject matter where necessary in terms more in accordance with standard U.S. claim drafting practice.

No new matter is added, and no change in inventorship is believed to result from amendment of the claims as proposed herein.

RESPONSE TO OFFICE ACTION DATED SEPTEMBER 5, 2006

1. Objection to Informalities

Claims 1–12 are objected to for containing the language “characterized in”. By amendment of Claims 1–12 herein, the phrases “characterized in that” and “characterized in” are replaced with “wherein”. The present objection is now moot and withdrawal of the objection is respectfully requested.

2. Obviousness-Type Double Patenting Rejection

Claims 1,2, 5–7 and 10–14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1–7 of copending application Serial No. 10/623,864. The rejection is provisional because the allegedly conflicting claims have not yet been patented. Applicant may elect to argue to overcome this ground of rejection or to provide a terminal disclaimer (to the extent necessary) once the present claims have been found to be otherwise allowable and/or once the '864 application issues as a patent.

3. Rejection under 35 U.S.C. §112

Claims 11–13 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The alleged indefiniteness arises from use of the word “type” appended to “silicone”. By amendment of Claims 11–13 herein, the word “type” is deleted. The present rejection is now moot and withdrawal of the rejection is respectfully requested.

4. Rejection under 35 U.S.C. §103(a)

Claims 1–14 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Zaffaroni (U.S. Patent No. 3,797,494) in view of Lee *et al.* (U.S. Patent No. 5,500,222), Klose *et al.* (U.S. Patent Application Publication No. 2004/0013620), Colley *et al.* (U.S. Patent No. 5,217,718), and Goodman & Gilman (1990). This rejection is respectfully traversed.

No admission is made herein that any document constitutes prior art to the present invention. It is particularly noted that the Klose document is not statutory prior art against the present invention, having published after the priority date of the present application. However, Klose claims priority *inter alia* to Reed *et al.* (U.S. Patent No. 6,299,900), which provides at col. 5, line 7 – col. 9, line 46 an extensive laundry list of drugs said to be deliverable through skin. Included in this extensive list are “dopamine-2 agonists such as S(-)-2-(N-propyl-N-2-thienylethylamino)-5-hydroxytetralin (N-0923)” (col. 6, lines 12–13). In responding to the present rejection, Applicant substitutes Reed (the ’900 patent) for Klose.

To establish a *prima facie* case of obviousness, three criteria must be satisfied: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. Absence of any one of these criteria is sufficient to overcome an allegation of *prima facie* obviousness. MPEP 2143.

According to the present Action, five documents are combined in order to arrive at the present ground of rejection. Such combination can only be made, impermissibly, by hindsight

reconstruction of the invention based on disclosure in the present specification. No motivation existed at the time of the present invention for one of ordinary skill in the art to combine the teachings of all five of these documents. Furthermore, no motivation is found in the primary reference or in generally available knowledge, even in view of the secondary references, to modify the primary reference to arrive at the present invention as defined in Claim 1. Therefore, because there is no motivation or suggestion to combine or modify the references, a *prima facie* case of obviousness has not been established.

Even if the five documents are somehow combinable (which is not admitted herein), the resulting combination fails to teach or suggest all claim limitations. The primary reference, Zaffaroni, proposes a bandage having a backing layer and a drug “reservoir”, which can, for example, take the form of a “pressure-sensitive adhesive, having distributed therethrough, ... a plurality of discrete microcapsules” (Zaffaroni, col. 3, lines 28–30) or “containers having one or more interior drug containing chambers, as well as solid matrices and microporous matrices having a systemically or topically active drug distributed therethrough” (Zaffaroni, col. 3, lines 48–52). However, even if the “microcapsules” or “chambers” of Zaffaroni are analogous to the microreservoirs of the present invention, Zaffaroni fails to disclose at least the following feature recited in Claim 1 of the present application: a matrix permeable to an amine functional drug in its free base form but impermeable to the drug in its protonated form.

None of the secondary references is found to supply these missing features, thus no combination of the cited documents teaches or suggests all the claim limitations, and accordingly a *prima facie* case of obviousness has not been established.

Notwithstanding the Examiner’s remarks with respect to Claims 2–14, these claims each embody all the limitations of Claim 1 from which they depend or which they reference and are therefore nonobvious at least for the same reasons that Claim 1 is nonobvious. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. MPEP 2143.03.

Thus the present rejection cannot be sustained because a *prima facie* case of obviousness has not been established. Failure of *prima facie* obviousness is shown at least

because no motivation exists to make the five-document combination cited. Alternatively, failure of *prima facie* obviousness is shown at least because no combination of the cited documents (even if motivation existed to combine them, which is not admitted) teaches or suggests all the claim limitations.

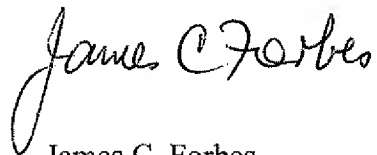
5. Conclusion

It is believed that all of the stated grounds of rejection are properly traversed, accommodated or rendered moot herein. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the present Action and that the application is in condition for allowance.

Should any issues remain, the Examiner is invited to call the undersigned at the telephone number given below.

Respectfully submitted,

HARNESS, DICKY & PIERCE, P.L.C.

A handwritten signature in black ink that reads "James C. Forbes". The signature is written in a cursive style with a large, stylized initial "J".

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